Serial No. 10/698,050
Filing Date: 10/30/2003

In the Claims

Applicants submit herewith a marked-up version of the claims. Entry of the amendments is requested. Please amend claims 1, 8 11, 12 and 33 as shown on the marked up versions of the claims. Please withdraw Claims 22-32.

The submitted marked-up versions of the claims follows standard amendment rules, wherein added text has been underlined and deleted text has been bracketed. The status of each claim is additionally provided.

Remarks to Amended Claims

Claims 1, 11, and 33 have been amended to specify that the analyte detector is for troponin, which would include a binding site for troponin. Support for this amendment is found throughout the specification. Specifically, support can be found at paragraphs [0003], [0006], [0011], [0027], [0028], [0030], [0032], [0039], [0048], [0066], [0073], [0074], [0075], [0076], and [0079] of the specification.

Claim 8 has been amended to indicate that the visible light energy is "emitting energy." Support for this amended is found at paragraph [0033] on page 6, where it is indicated that the "Light emitter 34 may comprise, for example, a laser diode that emits **visible light** in a narrow range of wavelengths. . ." **(emphasis added)**

Claim 11 has also been amended to reference an "implantable analyte detector" [originally "analyte detector implanted in a body of a patient"]. This amended is both inherently supported by the original claim language, as well as found throughout the specification. Specifically support for the implantable analyte detector can be found in paragraphs [0006], [0015], and [0032] of the specification.

Claim 12 has been amended to provide that at least one of the dyes is selected by changing the word "and" with the word "or" so that at least one dye is comprised from the compounds on the list. Support for this change is found starting on page 11, paragraph [0056] and continuing to page 12, paragraph [0061] where each dye is discussed in the alternative as a separate embodiment.

Claim 18 has been amended to reference "said light emitter and said light detector" of parent Claim 11. Support for this change is inherent from parent Claim 11, and so that Claim 18 appropriately references the light emitter(s) and detector(s) of Claim 11.

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Applicants' Response

Applicants respond below to each section of recent Examination by including (1) a restatement of the rejection/objection in single spaced type, followed by (2) Applicant's response in double space type.

Election/Restriction

Applicant's election with traverse of Invention I, Claims 1-21 and 33-37 in the reply filed on 11/28/05 was acknowledged, but was not found persuasive because the combination did not set forth the details of the subcombination as separately claimed, in particular the *plurality* of sensing elements anchored to a substrate. Furthermore, the Examiner found the subcombination has separate utility as an analyte measuring device used *outside* of the body and has practical applications that generally fall outside of the scope set forth in the combination.
The requirement was still deemed proper and was therefore made FINAL.

Applicants acknowledge the present restriction and have withdrawn Claims 22-32.

Claim Objections

Claim 12 was objected to because of the following informalities: on line 3, the word "and" should be replaced by "or" so that the dye is only one of the chemical compounds on the list.
Claim 18 was objected to because of the following informalities: the claim recites "wherein the a light emitter...". Appropriate correction is required.

Applicants wish to thank the Examiner for noting the need for the corrections to Claims 12 and 18. Applicants have amended Claim 12 to replace "and" with "or" so that at least one dye is chosen from the list of dyes. Similarly, Applicants have amended Claim 18 to reference "said light emitter and said light detector" of parent Claim 11.

Applicants indicate that the present objections to Claims 12 and 18 have been cured and respectfully request the present objection be removed.

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Claim Rejections under 35 USC § 112, Second Paragraph

Claim 8 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 8 recites the limitation "the energy is visible light". It was indicated to be unclear whether "the energy" refers to the illuminating energy, detected energy, or the energy exchanged between the dyes.

Claim 8 has been amended to indicate that the visible light energy is "emitting energy." Support for this amended is found at paragraph [0033] on page 6, where it is indicated that the "Light emitter 34 may comprise, for example, a laser diode that emits **visible light** in a narrow range of wavelengths ..." **[emphasis added]**

Applicants respectfully request the present reject be removed in view of the submitted amendment.

Claim Rejections under 35 USC § 101

1. Claims 11-21 were rejected under 35 U.S.C. 101 because the claimed invention was indicated to be directed to non-statutory subject matter. Claim 11 recites "an analyte detector implanted in a body of the patient...", which was found to improperly include a living subject as part of the claimed subject matter. The Examiner has indicated that the claim should be amended to recite "an analyte detector adapted to be implanted in..." to avoid this problem.

Applicants thank the Examiner for the suggested change to claims. Applicants have amended Claim 11 to reference an "implantable analyte detector" [versus an "analyte detector implanted in a body of a patient"]. Applicants believe indicating the detector is implantable as it avoids any possible interpretation that Claims 11-21, in whole or part, is directed to non-statutory subject matter.

In view of the submitted amendments, Applicants respectfully request the present rejection under 35 USC § 101 be removed.

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Claim Rejections under 35 USC § 102 over Chick et al.

Claims 1-8 and 10 were rejected under 35 U.S.C. 102(b) as being anticipated by Chick et al. (US Patent No. 6,040,194).

Regarding Claims 1 and 4-7, Chick et al. was cited for disclosing a method for detecting an analyte in the human body comprising placing an analyte detector with two fluorescent dyes within the body, illuminating the detector, and measuring the analyte concentration based upon the ratio of energy emitted by the two dyes as a result of fluorescent resonant energy transfer (FRET) between them (col. 2, line 31 – col. 6, line 44).

Regarding Claims 2-3, Chick et al, was cited for teaching a drug delivery system in communication with the analyte detector may be implanted in the body such that a feedback loop is established wherein a prescribed amount of drug is released when the measured analyte concentration exceeds a certain threshold (col. 6, lines 1-5).

Regarding Claim 8, Chick et al. was cited for teaching the illuminating energy is visible light at a wavelength of 472 nm (col. 11, lines 36-47).

Regarding Claim 10, Chick et al. was cited for teaching the analyte measured may be a narcotic such as cocaine or heroin (col. 5, lines 49-50).

Applicants have submitted amendments to the three standing independent claims (Claims 1, 11, and 33) to focus the scope of the present claims to an analyte detector for troponin. Although Chick et al. teaches a FRET detector system, no where in Chick et al. is there a teaching for making or using a troponin analyte detector or does Chick et al. suggest the merits of such a system.

Because a reference much teach each feature of the claimed invention, Applicants respectfully request the present rejection over Chick et al. be withdrawn.

Claim Rejections under 35 USC § 102 over Rao et al.

2. Claims 1, 4-8, 11, 17 and 19-21 were rejected under 35 U.S.C. 102(b) as being anticipated by Rao et al. (US Patent No. 5,628,310). Rao et al. discloses a system for measuring in vivo analyte concentrations using FRET comprising a visible light emitter 4, analyte detector 6 (with two fluorescent dyes and a glucose binding protein), light detector 18, and processor 28 (col. 19, line 31 – col. 20, line 9).
3. Regarding Claim 17, Rao et al. was also cited for disclosing a system with an alert module 32 to notify the patient based on the detection of a change in analyte concentration.

As previously indicated, Applicants have submitted amendments to the standing independent claims (Claims 1, 11, and 33) to focus the scope of the present claims to an analyte detector for troponin. Although Rao et al. teaches a

FRET detector system, no where in Rao et al. is there a teaching for making or using a troponin analyte detector. Furthermore, nowhere in Rao et al. is there a suggestion that such a use would be beneficial.

Because a reference much teach feature of the claimed invention, Applicants respectfully request the present rejection over Rao et al. be withdrawn.

Claim Rejections under 35 USC § 103 in view of Chick et al.

Claim 9 was rejected under 35 U.S.C. 103(a) as being unpatentable over Chick et al. as applied to Claim 1 above. Chick was cited for disclosing a method for detecting an analyte in the human body comprising placing an analyte detector with two fluorescent dyes within the body, illuminating the detector, and measuring the analyte concentration based upon the ratio of energy emitted by the two dyes as a result of fluorescent resonant energy transfer (FRET) between them. Chick teaches that the system is suitable for measuring many different types of analytes, including antigens (col. 5, lines 31-32). Although Chick does not make explicit reference to the cardiac troponin-T antigen, official notice is taken that this particular protein is a well-known antigen. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize the system as disclosed by Chick et al. to measure cardiac troponin-

To establish a prima facie case, the Examiner must show some suggestion or incentive that would have motivated the skilled artisan to modify a reference or to combine references. In re: Fine, 837 F.2d 1071, 1074, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988). Applicants respectfully assert that the Examiner has therefore failed to set forth a prima facie case of obviousness. There has been no evidence that the skilled artisan would have been motivated to modify the cited prior art reference or more importantly that Applicants' modifications would have a reasonable expectation of success. It is also clear that the prior art reference does not teach or suggest all the limitations of Applicants' claims directed to a troponin analyte detector as now indicated in Applicants' claims.

Obviousness must also be predicated on something more than that it would be obvious to try to make the claimed invention. In re Dow Chemical Co., 5 USPQ2d 1529 (Fed. Cir. 1987). In re Antonie, 195 USPQ2d 6 (CCPA 1977). The Examiner is merely suggesting that the combination claimed by the present invention would at best be "obvious to try" for one skilled in the art. Applicants remind the Examiner

that 'obvious to try' is not the standard under § 103. In re O'Farrell, 853 F.2d 894 (Fed. Cir.1988); Hybritech, Inc. v. Monoclonal Antibodies, Inc. 802 F.2d 1367, 1380 (Fed. Cir. 1986).

The Examiner has stated that official notice is taken that Troponin is a well known antigen. First, if the Examiner is making an official statement from personal knowledge, then a proper affidavit should be submitted. Even if Troponin is a well recognized antigen there is no teaching or suggestion to making the claimed troponin analyte detector system, or that such an analyte detector system would be operative. As previously discussed obvious to try is not the legal test for obviousness.

Because there is no teaching or suggestion to make the claim troponin analyte detector, Applicants respectfully request the present rejection under 35 USC §103 be removed.

Claim Rejections under 35 USC § 103 in view of Rao et al. in view of Kwon

Claim 12 was rejected under 35 U.S.C. 103(a) as being unpatentable over Rao et al. as applied to Claim 11 above, and further in view of Kwon (Pub.No. US 2003/0113934). Rao discloses a system for measuring in vivo analyte concentrations using FRET comprising a light emitter 4, analyte detector 6 (with two fluorescent dyes and a glucose binding protein), light detector 18, and processor 28, but does not disclose the particular types of fluorescent dyes used. Kwon discloses a system for monitoring analyte concentrations in the body using FRET, wherein one of the dyes which may be used is tetramethylrhodamine isothiocyanate. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use with the FRET system disclosed by Rao et al. the fluorescent dye tetramethylrhodamine isothiocyanate, since this dye allows for effective FRET analyte concentration measurements.

Claim 12 is dependent on Claim 11, and therefore contains the additional feature that the claimed system is for detecting troponin. Part of the inquiry for determining a prima facie case of obviousness under Section 103 has been discussed above.

Applicants respectfully assert that the Examiner has failed to set forth a prima facie case of obviousness. Even if tetramethylrhodamine isothocyanate is a well recognized dye, there is no teaching or suggestion to combine the fluorescent dye

with troponin to make the claimed analyte detection system, or that such an analyte system for troponin would be operative. As previously discussed "obvious to try" is not the legal test for obviousness.

Because there is no teaching or suggestion to make the claim troponin analyte detector, Applicants respectfully request the present rejection under 35 USC §103 removed.

Claim Rejections under 35 USC § 103 over Rao et al. in view of Chick et al.

Claims 13-16 were rejected under 35 U.S.C. 103(a) as being unpatentable over Rao et at. as applied to Claim 11 above, and further in view of Chick et al. Rao discloses a system for measuring in vivo analyte concentrations using FRET comprising a light emitter 4, analyte detector 6 (with two fluorescent dyes and a glucose binding protein), light detector 18, and processor 28. Rao was also cited to indicate that the system may be in communication via a modem or antenna with an external diagnostic device (col. 1, lines 15-28), but does not explicitly disclose that the processor 28 compares the measured analyte concentration to a threshold and communicates the result to a therapy device. Chick was cited for disclosing a FRET analyte monitoring system that communicates with a drug delivery device implanted in the body such that a feedback loop is established wherein a prescribed amount of drug is released when the measured analyte concentration exceeds a certain threshold. It would have been obvious to one having ordinary skill in the art at the time the invention was made to place the analyte monitoring device as disclosed by Rao et al. in communication with a therapy device as taught by Chick et al. since this allows for a feedback loop to be established.

Claims 33-37 were also rejected under 35 U.S.C. 103(a) as being unpatentable over Rao et al. in view of Chick et al. Rao was cited, as above, for disclosing a system for measuring in vivo analyte concentrations using FRET comprising a light emitter 4, analyte detector 6 (with two fluorescent dyes and a glucose binding protein), light detector 18, and processor 28. Rao further indicates that the system may be in communication via a modem or antenna with an external diagnostic device (col. 1, lines 15-28), but does not explicitly disclose that the processor 28 compares the measured analyte concentration to a threshold and communicates the result to a therapy device. Chick discloses a FRET analyte monitoring system that communicates with a drug delivery implanted in the body such that a feedback loop is established wherein a prescribed amount of drug is released when the measured analyte concentration exceeds a certain threshold. The Examiner conclude it therefore would have been obvious to one having ordinary skill in the art at the time the invention was made to place the analyte monitoring device as disclosed by Rao et al. in communication with a therapy device as taught by Chick et al. since this allows for a feedback loop to be established.

Claim 13-16 is dependent on Claim 11, and therefore contains the additional feature that the claimed system is for detecting troponin. Claims 33-37 also contains the additional features for detecting troponin.

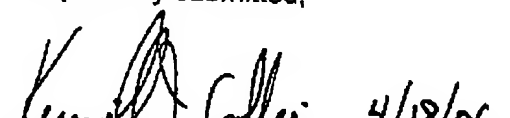
Applicants respectfully assert that the Examiner has failed to set forth a prima facie case of obviousness based on the prior discussion that there is no teaching or suggestion to combine the fluorescent dyes with troponin to make the claimed detection system, or that such an analyte system for troponin would be operative. As previously discussed "obvious to try" is not the legal test for obviousness.

Because there is no teaching or suggestion to make the claim troponin analyte detector, Applicants respectfully request the present rejection under 35 USC §103 over Rao et al. in view of Chick et al. removed.

Conclusion

Applicants indicate they believe they have addressed all the issues raised by the Examiner, and respectfully request that the invention as now claimed be allowed to issue.

Respectfully submitted,



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